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No. 80-259

IN THE

Supreme Court of the United States

OCTOBER TERM, 1980

GLEN L. RUTHERFORD, *et al.*,
Petitioners

v.

UNITED STATES OF AMERICA, *et al.*,
Respondents

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Tenth Circuit

MOTION FOR LEAVE TO FILE BRIEF AMICUS CURIAE AND BRIEF AMICUS CURIAE OF THE AMERICAN CANCER SOCIETY, INC. IN OPPOSITION TO THE PETITION FOR CERTIORARI

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MOTION FOR LEAVE TO FILE BRIEF AMICUS CURIAE

The American Cancer Society, Inc. ("Society") respectfully requests leave to file *instanter* the written brief *amicus curiae* in support of the United States' opposition to the petition for writ of certiorari. The interest of the Society and a chronology of its participation in the proceedings involving laetrile which preceded and are related to this petition for certiorari are detailed on the "Statement of Interest" in the attached brief. Succinctly stated the Society participated (a) in the laetrile rule-

making proceeding before the Food and Drug Administration; (b) as *amicus curiae* without opposition in the proceedings before the United States Court of Appeals for the Tenth Circuit which were reviewed on petition for certiorari by this Court in Docket No. 78-605; *United States* v. *Rutherford;* and (c) this Court on motion permitted the Society to participate as *amicus curiae* in the proceedings in Docket No. 78-605 which resulted in this Court's opinion of last June, 442 U.S. 544.

By letter of August 18, the Society requested a letter of consent to participate as *amicus curiae* from the United States and from Petitioner Rutherford.

By letter of August 25, 1980, the Solicitor General of the United States, Wade H. McCree, Jr., consented to the filing of a brief *amicus curiae* on behalf of the American Cancer Society in the Supreme Court in this case.

On September 12, counsel attempted to reach Kirkpatrick Dilling, one of the counsel for Petitioner Rutherford, to ascertain why no response had been received to the Society's letter of August 18 requesting permission to participate as *amicus curiae* in this proceeding. Counsel was informed that Mr. Dilling was out-of-the-country until September 24, 5 days after the date on which the Society's brief would have to be filed with this Court. However, Mr. Gronek, one of Mr. Dilling's partners, agreed to check his files for any instructions relating to the Society's request. By telephone conversation of September 15, Mr. Gronek stated that he would be unwilling to make a decision for his partner and that the question would be referred to Mr. Dilling on his return.

On September 12, 15 and 16, counsel also telephoned the office of Kenneth Coe, another of Petitioner's Counsel. Although repeated messages were left requesting a response to the Society's letter seeking consent to participate as *amicus curiae*, Mr. Coe did not return these calls.

While the Society supports the position of the Petitioner, the United States, its brief presents a different perspective, one which is in keeping with the role of the Society.

The Society is a voluntary organization fighting cancer through balanced programs of research, education, patient service and rehabilitation. The American public and the medical profession look to the Society for the most up-to-date and accurate information about cancer. Without the widespread dissemination of accurate information, such as that provided by the Society, the goal of further reducing the ravages of cancer through early diagnosis and treatment would unquestionably be more difficult to achieve.

Inasmuch as early and proper treatment of cancer is a life-and-death matter, unjustified deviations from this desideratum are of concern to the Society. One of the areas in the forefront of public and professional questioning addressed to the Society pertains to unproven methods of cancer management, e.g. laetrile.

It is from this perspective that the Society approaches participation as an *amicus curiae* in this proceeding. The Society's brief is not a repetition of arguments made by the Petitioner or, we anticipate, by the United States, but rather deals with and contains matter related to the impact of the Court of Appeals decision requiring application of the premarketing clearance provisions of the federal drug laws to laetrile both on the terminally ill as well as on those with life-threatening illness. The Society's brief deals with the issues of the role of the federal government with respect to the regulation of drugs in a manner and from a viewpoint different from that of the other parties.

The Society believes, in view of the nature of the case at bar, and the arguments urged or anticipated from the

parties, that its arguments and information will assist the Court in its decision on the petition and that the Society should therefore be granted leave to file its brief *amicus curiae* in support of the Government.

Respectfully submitted,

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BRIEF AMICUS CURIAE OF THE AMERICAN CANCER SOCIETY, INC. IN OPPOSITION TO THE PETITION FOR CERTIORARI

STATEMENT OF INTEREST OF THE AMERICAN CANCER SOCIETY

The American Cancer Society has a substantial interest in the outcome of this proceeding. Briefly stated, the American public and the medical profession look to the American Cancer Society and its 58 chartered Divisions and 2,964 local units, to provide the most up-to-date and accurate information about cancer. In most

cases early and effective treatment of cancer is a life and death matter. One of the major concerns expressed by the public and the medical profession in questions addressed to the Society pertains to unproven methods of cancer treatment. To respond to the need for information in this area the Society has established a committee on unproven methods and maintains one of the world's largest reference centers for the collection and dissemination of data concerning cancer. To further its obligation to the public and the medical profession to uncover and disseminate the facts relating to unproven methods of cancer treatment, the Society participated in the Rutherford proceedings on the rulemaking level [1] and in the capacity of *amicus curiae* in the proceedings on appeal which are the subject of this petition including the appeal which was resolved by this court's decision of June 18, 1979, in *Rutherford* v. *United States*, 442 U.S. 544.

Mr. Rutherford's petition challenges the existing statutory protection against ineffective methods of cancer treatment contained in state and federal drug laws. If the current requirements of safety and efficacy fall, the patient/consumer and the practicing physician will be deprived of their first line of defense against ineffective drugs. It is as true today as it was when President Kennedy requested legislation assuring the efficacy of drugs that:

> . . . There is no way of measuring the needless suffering, the money innocently squandered, and the protraction of illnesses resulting from the use of . . . . ineffective drugs.

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[1] Rutherford v. United States, 438 F. Supp. 1287 (W.D. Okla. 1977) affirmed on other grounds, 582 F.2d 1234 (10th Cir. 1978) reversed and remanded, 442 U.S. 544 (1979) opinion reversing district court on remaining grounds, 616 F.2d 455 (1980).

> The physician and consumer should have the assurance from an impartial scientific source that any drug or therapeutic device on the market today is safe and effective for its intended use . . . .[2]

The impact of the Appeals Court's decision which prevents circumvention of federal drug standards of safety and efficacy by either a "right of privacy" or grandfathering rationale will obviously affect the Society in its role as a primary source of information for the general public and the medical profession for accurate information on unproven methods of cancer treatment.

In sustaining the validity of the pre-marketing clearance requirements of the federal drug laws, the Court of Appeals has effectively closed one of the floodgates that would encourage the marketing of an unproven cancer treatment. The decision affirms a reasonable pre-market standard. It protects victims of cancer, who, when confronted with a life-threatening illness, are particularly susceptible to cures promised by use of a worthless and therefore unsafe and dangerous drug. The Society's interest lies in speaking out for the continuation of the proper balance of manufacturer and consumer interest which currently exists in the statutory scheme regulating drugs. It would be a great disservice to the public if a decision affirming the balanced regulatory scheme was undermined by a petition which, as demonstrated below, is unsound as a matter of law.

The American Cancer Society has received the consent of counsel for the United States to file this brief *amicus curiae* in accordance with Rule 42 of this Court. That permission is attached to the original of this brief filed with the Supreme Court.

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[2] Statement of John F. Kennedy to Congress, March 15, 1962, in support of the 1962 Amendment to the Federal Food, Drug and Cosmetic Act. 108 Cong. Rec. 4169, 1962 U.S. Code Cong. & Admin. News at 4143.

REASONS FOR DENYING THE PETITION FOR WRIT OF CERTIORARI

I. THE FEDERAL APPEAL'S COURT DECISION ON THE PROCEDURAL ISSUES RAISED BY PETITIONERS IS IN ACCORD WITH ACCEPTED JUDICIAL PROCEDURE AND WITH THE DECISIONS OF THIS COURT AND OTHER FEDERAL APPELLATE COURTS

A. Introduction

Petitioners claim that the administrative proceeding by the Food and Drug Administration to determine whether laetrile meets the requirements of the Food, Drug and Cosmetic Act was improperly conducted. Petitioners allege that the procedure utilized in this hearing violated statutory protections and constituted an abuse of discretion by the Food and Drug Administration (hereinafter "FDA"). The analysis of specific arguments advanced by petitioners reveals not only that the proceedings was conducted within the bounds of statutory requirements and agency discretion, but that Petitioners failed to object to the procedures proposed to be employed by the FDA spelled out in notices in the Federal Register prior to the proceeding's commencement. Thus, the Petitioners did not, by appropriate comment in advance of hearing, provide the agency with an opportunity to modify any procedures it argued were defective. Petitioners are now attempting to profit from their silence by raising these issues before the Court.[3]

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[3] These issues were also raised in briefs to the Federal Appeals Court and to this court on certiorari in United States v. Rutherford, 582 F.2d 1234 (10th Cir. 1978) revised and remanded, 442 U.S. 544 (1979). See e.g. Brief of Respondents before this court in Docket No. 78-605, pp. 29-30. It is questionable whether Petitioners still have standing to raise them here.

B. Petitioners' Claim that the Absence of an Opportunity for Cross Examination is Grounds for Reversing the Decision of the Federal Appeals Court finds no Support in the Legal Authority Relied Upon and Conflicts with the Basic Principles of Administrative Procedure

Petitioners allege that the denial of an opportunity for cross-examination "belied any openminded review by the Food and Drug Administration." (Petitioner's Brief, p. 21) Yet, Petitioners hands are far from clean on this issue. On February 8, 1977, a notice was placed in the Federal Register detailing the procedures to be used by the FDA and announcing that oral argument was scheduled on May 2, 1977.[4] During the interim, petitioners failed to object to these announced procedures. Only at the last stage of the rulemaking procedure—the hearing in Kansas to take testimony by oral argument, did the Petitioners object.[5] Petitioners should not be permitted to profit from their silence by obtaining a writ of certiorari on this basis.

Moreover, petitioners are incorrect in their assertion that the Administrative Procedure Act establishes a right to cross-examination in this proceeding. (Petitioners Brief, p. 22) Petitioners rely upon 5 U.S.C. 556(d) to establish their alleged right to cross-examination in this proceeding. Section 556(b) clearly states that "[T]his subchapter does not supersede the conduct of specified classes of proceedings, in whole or in part, by or before boards or other employees specially provided for by or designated under statute." 5 U.S.C. 556(b)

The Administrative Procedure Act explicitly provides that it shall not supersede hearing procedures established pursuant to another statute. The hearing in question

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[4] 42 Federal Register 10066 et seq. (1977).

[5] TR. 10.

took place pursuant to § 2.14 of the FDA's Practices and Procedures (42 Fed. Reg. 4706) which is currently incorporated in the Code of Federal Regulations as 21 C.F.R. 10.60. These Administrative Practices and Procedures have been promulgated pursuant to extensive statutory authority,[6] including but not limited to the Food, Drug and Cosmetic Act.[7]

Because § 2.14 empowers the Commissioner, in the exercise of discretion, to conduct hearings on matters referred by courts without providing for cross-examination, this source of authority supersedes any conflicting requirements of the Administrative Procedure Act. Petitioners' reliance upon the Administrative Procedure Act to object to the FDA proceeding is therefore misplaced.

C. Petitioners' Objection that the FDA hearing was Conducted by the most Informal Procedures Allowed is Factually Incorrect; the Procedure Selected Represents a Legitimate Exercise of Agency Discretion

Petitioners allege that the lack of an openminded review by the Food and Drug Administration is evidenced by the Commissioner's decision to conduct hearings under provisions for the most informal proceedings allowed. (p. 21) This statement is inaccurate. Under 21 C.F.R. 10.60(c), the Commissioner may use his discretion to employ less formal procedures than those which were used, to reach a determination on matters referred by federal, state, or local courts. For example, 21 C.F.R. 10.60(c)(1) permits a determination by conferences,

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[6] 21 U.S.C. 321 *et seq.*; 42 U.S.C. 201 *et seq.*; 42 U.S.C. 257a; 21 U.S.C. 821 *et seq.*; 21 U.S.C. 679(b); 21 U.S.C. 1031 *et seq.*; 21 U.S.C. 141-149; 21 U.S.C. 41-40; 15 U.S.C. 401 *et seq.*; 15 U.S.C. 1451 *et seq.* Statutory Authority pursuant to which FDA Rules of Practice and Procedure were promulgated.

[7] 21 C.F.R. 10.1(a).

meetings, discussions, and correspondence pursuant to 21 C.F.R. 10.65. In addition, 21 C.F.R. 10.60(c)(7) permits a determination based upon data, information, and views with no oral testimony received pursuant to the publication of a notice in the Federal Register.

The proceedings employed by the Commissioner were not the least formal method of review as Petitioners allege. These hearing procedures represented a legitimate exercise of agency discretion in choosing a set of hearing procedures best suited to assist the Commissioner in reaching a decision given the diverse nature of the consumer, scientific, medical population concerned as well as the folk medicine nature of the drug involved. It is not the function of the Court to second-guess the exercise of discretion legitimately exercised under agency regulations.[8]

D. Petitioners' Objection that the Record Compiled by the Food and Drug Administration did not Meet the Standards Set Forth by the Federal Appeals Court is Refuted by the Court of Appeal's Willingness to Review this Record

Petitioners assert that the FDA's administrative hearing did not meet the standards set forth by the United States Court of Appeals for the Tenth Circuit, 542 F.2d 1137, 1143-4 (10th Cir. 1976) (Petitioners Brief, pp. 21-22). However, recognizing that laetrile is an alleged folk medicine with no established or organized proponents, the Court of Appeals found that the 5,500 pages of written submissions and two days of oral hearings constituted an acceptable record and proceeded to so review it. *Rutherford* v. *United States*, 616 F.2d 455, 456 (10th Cir.), see also 582 F.2d 1234, 1236 (10th Cir. 1978).

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[8] Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, Inc., 435 U.S. 519 (1978); United States v. Florida East Coast Ry., 410 U.S. 224 (1973).

The FDA's record was deemed acceptable for review by the Tenth Circuit. That court has not been shy in the past to turn away records which it did not deem acceptable for review. That court mandated the laetrile rulemaking proceeding because it considered the record presented for review on laetrile was insufficient.[9] The appeals court did not find the laetrile rulemaking proceeding record similarly insufficient. It is not the function of the Supreme Court to substitute its own opinion for that of the Court of Appeals in reviewing the record.[10] Petitioner's request that this Court second-guess the Court of Appeals on the adequacy of the record therefore exceeds the proper scope of review by this Court.

E. The Federal Appeals Court Properly Placed the Burden of Proof Upon Petitioners to Demonstrate that Laetrile was Subject to the Grandfather Clause of the 1962 Act

Petitioners object that the Federal Appeals Court improperly shifted the burden of proof involving whether laetrile met the requirements of the grandfather clause from the FDA to Petitioners. (Petitioner's Brief, p. 20) There is no error on this issue in the Federal Appeals Court opinion.

The federal appeals court at the interlocutory stage of this proceeding at which it remanded for a rulemaking proceeding had, in *dicta*, stated that "[T]o support its determination [that laetrile is a new drug] the FDA in the case at bar would have to present substantial evidence to support the proposition that laetrile is not gen-

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[9] Rutherford v. United States, 542 F.2d 1137, 1143-3 (10th Cir. 1976).

[10] NLRB v. Pittsburgh Steamship Co., 340 U.S. 498 (1951); FTC v. Standard Oil Co., 355 U.S. 396 (1958); Universal Camera Corp. v. NLRB, 340 U.S. 474 (1951); FTC v. American Tobacco Co., 274 U.S. 543 (1927).

erally recognized among qualified experts as 'safe and effective,' and that laetrile is not grandfathered . . . ." 542 F.2d 1137 at 1143 (10th Cir. 1976). That *dicta*, relied on by Petitioners, did not represent the decisions of this Court,[11] and was in conflict with the decisions of other federal courts passing upon the same issue.[12]

No matter how a drug becomes the subject of an FDA rulemaking proceeding either by agency initiative, manufacturer or other drug proponent initiative or court referral, the burdens of proof and proceeding and the standards of review established by the federal drug laws as construed by the courts are the same. The statute and regulations do not require the Food and Drug Administration to prove a drug ineffective but rather, the burden of proceeding and proof of safety/efficacy by a substantial amount of well documented evidence lies with the proponents of the drug.[13]

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[11] See e.g. Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 617 (1973); Weinberger v. Bentex Pharmaceuticals, Inc., 412 U.S. 645, 652 (1973); USV Pharmaceutical Corp. v. Weinberger, 412 U.S. 655, 660 (1973). Nor does it represent other federal decisions relied upon by this court. See e.g. Ubiotica Corp. v. FDA, 427 F.2d 376, 378 (6th Cir. 1970); Upjohn Co. v. Finch, 422 F.2d 944, 955 (6th Cir. 1970); North American Pharmacal, Inc. v. HEW, 491 F.2d 546, 550-51 (8th Cir. 1973).

[12] See e.g., Julian H. Morgan, Sr. et al. v. David Matthews et al., Civil Action No. 76-1636 (D. South Carolina) Opinion of Judge Chapman, November 30, 1976 (laetrile case); Tutoki v. Celebreeze, 375 F.2d 105 (7th Cir. 1967) (krebiozen); Rutherford v. American Medical Ass'n, et al., 379 F.2d 641 (7th Cir. 1967) (cert. den., 389 U.S. 1043). See also H. Rept. No. 2139, 75th Cong., 3rd Session (April 14, 1938) at p. 9 and H.R. Rept. No. 2464, 87th Cong., 2nd Sess. (Sept. 22, 1962) pp. 3, 5 which make it clear that the burden of presenting evidence that a product is not a new drug lies with the manufacturer.

[13] See Rutherford v. United States, 616 F.2d 455, 457 (10th Cir. 1980) citing United States v. Allan Drug Corporation, 357 F.2d 713 (10th Cir. 1966), cert. denied, 385 U.S. 899 (1966).

The Federal Appeals Court corrected its prior error by the opinion before this Court on petition for certiorari. The appeals court properly held that the statute, case law and agency procedures all place the burden of proof upon the party seeking the grandfather clause exception.[14]

II. THE FEDERAL APPEALS COURT HAS DECIDED THE GRANDFATHER CLAUSE AND RIGHT OF PRIVACY ISSUES IN ACCORDANCE WITH THE APPLICABLE DECISIONS OF THIS COURT AND IN CONCERT WITH THE DECISIONS OF ITS SISTER FEDERAL APPEALS COURTS ON THE SAME ISSUES

A. The Petitioners do not Set Forth Any Actions of The Federal Appeals Court Pertaining to Disposition of the Grandfather Clause Issue that Warrant Review by This Court

1. *Petitioners Inappropriately Seek Review of Factual Findings; Petitioners Allege Appeals Court Error on Only One of the Four Criteria Which Must be Met to Receive Coverage of the Grandfather Clause*

It is a well settled position of this Court that it will not ordinarily grant certiorari to review evidence, discuss specific facts or to review judgments based solely on questions of fact. See e.g., *United States* v. *Johnson*, 268 U.S. 220 (1925), *General Talking Pictures Corp.* v. *Western Electric Company*, 304 U.S. 175 (1938) and *National Labor Relations Board* v. *Waterman Steamship Corp.*, 309 U.S. 206 (1940). Yet this is exactly the activity which Petitioner would have the Court undertake. Petitioners' substantive[15] attack on the appeals court's

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[14] See notes, *supra*.

[15] The procedural objections by Petitioners to the federal appeals court's application of the grandfather clause are covered in Part I of this brief, *supra*.

application of the criteria in the grandfather clause contained in the 1962 Amendments relates to matters of fact:

> "Appeal Court's recent opinion herein misconstrues the factual circumstances and also the factors involved as to the "grandfathering" of Laetrile, or amygdalin . . . ." Petitioners Brief at p. 18.

Then, although the 1962 grandfather clause contains four criteria [16] all of which must be satisfied to invoke its coverage,[17] Petitioner alleges appeal court error of fact on only one of the grandfather requirements, that relating to consistency in formula. See Petitioner's Brief at page 18. As to the other grandfather criteria:

(a) *Safety*

Petitioner refers to the findings of the district court which it considers preferable on the "safety" criteria. See Petitioners Brief at pp. 23-24. However, Petitioners

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[16] Entitlement to the grandfather exemption of the 1962 amendments, *i.e., Section 107(c)(4) of the Food and Drug Act,* is limited to drugs which: (1) feature *today* the identical chemical composition recommended dosages, and claims made in labeling as existed on October 9, 1962, and (2) were used or sold commercially in the United States on October 9, 1962, and (3) were generally recognized by the experts as safe; and (4) were not covered by an effective drug application. See United States v. Allan Drug Corp., 357 F.2d 713, 718-19 (10th Cir. 1966), cert. denied, 385 U.S. 899; United States v. 1,048,000 Capsules, More or Less, 347 F. Supp. 768 (S.D. Tex. 1972), aff'd 494 F.2d 1158 (5th Cir. 1974); see also Rutherford v. United States, 542 F.2d 1137, 1141 (10th Cir. 1976). The Commissioner concedes issue No. 4 in the Notice of Rulemaking.

[17] See e.g. United States v, Allan Drug Corp., *supra.* Accord Durovic v. Richardson, 479 F.2d 242, 250 n.6 (7th Cir. 1973), cert. denied, 414 U.S. 944 (1973); United States v. An Article of Drug . . . Bentex Ulcerine . . ., 469 F.2d 875, 878 (5th Cir. 1972), cert. denied, 412 U.S. 938 (1973); United States v. 1,048,000 Capsules, More or Less, et al., 347 F. Supp. 768, 770 (S.D. Tex. 1972), aff'd 494 F.2d 1158 (5th Cir. 1974).

make no attempt to set forth let alone support any error in the differing Federal Appeals Court's finding on this issue.

(b) *Commercial Use and Sale*

Petitioners do not even address the "commercial use and sale" requirement of the grandfather clause.

As noted above, all grandfather criteria must be met to gain the coverage of the clause. Petitioners have identified an alleged defect in the appeals court's opinion only as to one of the clause's criteria.[18] This solitary alleged error is factual and would not support review even if correct. Petitioners have not specified findings of the appeals court in error on the rest of the grandfather clause criteria which must be satisfied to gain the relief sought, Petitioners do not make a showing which warrants review by or relief from this Court.

2. *The Federal Appeals Court has Decided the Grandfather Issue in Accordance with the Provisions of the Federal Drug Laws*

Petitioners' pleading, as set forth in the preceding section, does not articulate reasons supporting a grant of certiorari. Moreover, scrutiny of the appeals courts decision against accepted standards of review and the record before the court demonstrate that there is no error in that court's action.

The Commissioner's Laetrile Rulemaking decision is subject to the standards of court scrutiny applicable to review of agency action. The review court is required to view the record as a whole[19] and determine whether

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[18] The Society submits that the issues are not presented with the detail or the clarity needed for effective adjudication and that review is not appropriate. See Socialist Labor Party v. Gilligan, 406 U.S. 583 (1972).

[19] See Diamond King Ranch, Inc. v. Morton, 531 F.2d 1397, 1405 (10th Cir. 1976).

the Commissioner had articulated the grounds of his decision, whether those grounds are consistent with the statute, and whether those grounds are supported by the evidence of record. In short, if the Commissioner's decision shows that the FDA has a reasonable basis for considering that the drug proponent's submissions did not comply with the substantial evidence requirements of the statute and regulations, the Commissioner's decision should be affirmed.[20] The 10th Circuit articulated this standard for review in *Sabin* v. *Butz*.[21]

> . . . . the ultimate standard of review is a narrow one. The court is not empowered to substitute its judgment for that of the agency. Id. The court's function is exhausted where a rational basis is found for the agency action taken. Udall v. Washington, Maryland, and Virginia Coach Co., 130 U.S. App. D.C. 171, 398 F.2d 765, 769, cert. denied, Washington Metropolitan Area Transit Com. v. United States, 393 U.S. 1017, 89 S.Ct. 620, 622, 21 L.Ed. 2d 561.

Application of this standard of proof and review criteria supports the conclusion reached by the Commissioner, and affirmed by the appeals court's reversal of the district court's findings, namely that the drug Laetrile does not satisfy any of the elements of the 1962 grandfather clause:[22]

> It is apparent . . . that the several requirements of the 1962 amendments are not in the alternative, but instead each must be met. It is also apparent that with the folk medicine aspect of the use of Laetrile the several requirements cannot be met.

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[20] Sabin v. Butz, 515 F.2d 1061, 1067 (10th Cir. 1975).

[21] Id.

[22] See generally on the lack of general recognition of safety/efficacy; inconsistency in formulation, dosages and labelling claims and investigational as opposed to commercial use, the Commissioners Opinion, 42 Fed. Reg. at pp. 39790-39795.

> This is especially so as to the consistent labeling requirements since October of 1962. The record also demonstrates, not unexpectedly, that there has not been the consistency in the formula which the FDA requires under its current practice. In short, the record does not support a conclusion that the several conditions in Pub.L. 87-781 have been met to permit the application of the grandfather exceptions. In United States v. Allan Drug Corporation, 357 F.2d 713 (10th Cir.), a condemnation case, we considered the 1962 amendments. We there said: "Since we are dealing with a Grandfather Clause exception, we must construe it strictly against one who invokes it." [23]

Petitioners have not demonstrated any error that requires this Court to grant certiorari.

III. THE FEDERAL APPEALS COURT HAS DECIDED THE RIGHT OF PRIVACY ISSUE IN ACCORDANCE WITH THE APPLICABLE DECISIONS OF THIS COURT

Petitioners seek an exemption for the terminal in choosing laetrile on constitutional grounds that parallel the exemption by statutory construction rejected by this Court in its *Rutherford* opinion. 442 U.S. 544 (1979) This Court in the closing paragraph of *Rutherford* states that the Act's

> "explicit provision for carefully regulated use of certain drugs not yet demonstrated safe and effective reinforces our conclusion that no exception for terminal patients may be judicially implied."

Although this analysis deals with statutory construction, its rationale is equally persuasive against the background of this Court's decisions on a right of privacy vis a vis choices of medical treatment. Cancer victims constitute

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[23] Rutherford v. U.S., 616 F.2d 455, 457.

a minority in our society; terminal cancer patients constitute an even smaller minority, but like other groups, they have a right not to be exploited. In the case of cancer drugs, particularly the exercise of government power of protection, premarket clearance is not only reasonable, but necessary to protect the compelling public interest in effective cancer therapy, and in assuring that non-therapeutic drugs do what they say. In view of the widespread incidence of cancer, the serious consequences of the disease, the experience with the particular vulnerability of cancer patients and their families to promoters of easy money-making schemes labeled in mysterious scientific dress, it is imperative that the standards of consumer protection set forth in the federal drug acts be maintained.

The Court of Appeals answered in the negative the question of whether there is a right of privacy inhering in the Constitution to choose medication for cancer that has not passed the premarketing clearance standards of the federal drug laws. The appeals court held that there was no such fundamental right and that the rational relationship tests applied to measure the ambit of the right claimed. The appeals court's decision followed on the heels of a decision by the highest court in California that held that the premarketing clearance requirements of the federal and state drug laws bear a reasonable relationship to the protection of public health by limiting a patient's choice of medications.[24] Petitioners claim that the compelling governmental interest test should apply and derides the lack of exhaustive case analysis by the appeals court. (See 616 F.2d 455 and Petitioners Brief, pp. 28-29) Exhaustive case analysis is not called for in here. The cases cited by the appeals

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[24] People v. Privitera, 23 Cal. 3rd 697, 153 Cal. Reptr. 431, 591 P.2d 919 (1979), cert. denied, 444 U.S. 949 (1979).

court speak for themselves and support the standard of proof applied.[25]

Both the Federal Appeals Court and the Supreme Court of California rested their decisions on this Court's decisions in *Planned Parenthood of Missouri* v. *Danforth*, 428 U.S. 52 (1976); *Roe* v. *Wade*, 410 U.S. 113 (1973); and *Whalen* v. *Roe*, 429 U.S. 589 (1977).

Planned Parenthood of Missouri v. *Danforth* holds that choice among medical alternatives is not at this time a decision within the zone of constitutionally protected privacy. That decision stands for the proposition that although a decision of whether to have an abortion is within the constitutional zone of privacy, deserving the protection provided by the "compelling interest" standard, the selection of a particular abortion procedure is a medical matter to which privacy status does not attach and which may be regulated by government, provided a rational basis for such regulation exists.

In the instant case, the analogue of the right to decide whether to have an abortion is the right to decide whether to receive or forego cancer treatment. Although the decision whether to receive treatment may be constitutionally protected, the choice among treatment alternatives is not within the scope of the constitutional right to privacy. In *Planned Parenthood* the issue was whether the regulation reasonably relates to the preservation and protection of maternal health. Its analogue here is whether the rulemaking provisions of the federal drug laws reasonably relate to the preservation and pro-

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[25] Whalen v. Roe, 429 U.S. 589 (1977); Planned Parenthood of Missouri v. Danforth, 428 U.S. 52 (1976); Paris Adult Theatre I v. Slaton, 413 U.S. 49 (1973); Roe v. Wade, 410 U.S. 113 (1973); Doe v. Bolton, 410 U.S. 179 (1973); and Eisenstadt v. Baird, 405 U.S. 438 (1972); see also People v. Privitera, 23 Cal. 3d 697, 153 Cal. Reptr. 431, 591 P.2d 919 (1979), U.S. cert. den., 444 U.S. 949 (1979).

tection of the health of the cancer patient. The highest court of the state of California and the federal appeals court correctly held that the state statute establishing a safety and efficacy standard reasonably relates to the preservation and protection of the health of cancer patients.

Roe v. *Wade* is significant in light of the constitutional issue raised, for it reflects this Court's recognition of the government's compelling interest in protecting individual health, and in protecting the public health generally where individual conduct may adversely affect the well-being of others. This court's decision in *Roe* holds that at some point during pregnancy the state's important interest in safeguarding health, in maintaining medical standards, and in protecting potential life became sufficiently compelling to sustain regulation of the factors that govern the abortion decision. The authority to protect individual health, and the public health generally, may be exercised to overrule the woman's personal decision to undergo a particular medical or surgical procedure during the second and third trimesters of pregnancy even when she is fully aware of the risks of the procedure, and is willing to take those risks.[26]

An individual's decision to use Laetrile can stand on no higher constitutional level than the decision of a woman to have an abortion in the later stages of pregnancy. The Commissioner's Laetrile Opinion makes clear the parallels between *Roe* and the case presented for review.[27] It was established in the Commissioner's Opinion on Laetrile that a significant number of cancer patients can be cured or have their lives extended by the use of effective therapy, especially when treatment is be-

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[26] 410 U.S. at 162-165.

[27] E.g., the FDA rulemaking decision on laetrile, Laetrile, Commissioner's Decision, 42 Fed. Reg. 39768, 39782 (1977).

gun as soon as possible after diagnosis.[28] The availability of Laetrile serves to encourage delay among certain cancer patients in seeking effective therapy.[29] Moreover, even among patients who begin treatment of their cancers with effective therapy, the readily acknowledged side effects of that therapy may cause them to cease to use such methods at a time when their application still may be successful, and turn instead to Laetrile—"a painless cure." Because legitimate therapy may be stopped, delayed or avoided, many cancer patients will die needlessly or prematurely. This fact alone provides compelling justification for an even more stringent criteria than that relied upon by the federal appeals court and the California court for prohibiting interstate transportation and sale of drugs such as Laetrile absent compliance with the premarketing standards that are contained in federal drug laws and the California code.

Further, the appeals court's decision finds support in the rationale set forth by this Court in *Whalen* v. *Roe*, *supra*. There, the Court upheld a state statute requiring physicians to report the names and addresses of patients for whom the physicians had prescribed certain dangerous drugs to a state agency. The patients contended, among other things, that the statute invaded their constitutionally protected zone of privacy by depriving them of the right to decide independently, with the advice of a physician, to acquire and use needed medication. The Court upheld the statute, citing cases using ordinary, not "compelling interest" tests for the exercise of the police power and concluded that the impact of the statute on either the reputation or the independence of patients for whom the specified drugs are medically indicated is not sufficient to constitute an invasion of any right or liberty

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[28] Id. at 39799.

[29] Id. at 39797, 39799.

protected by the Fourteenth Amendment. 429 U.S. at 603-604.

Finally, *Eisenstadt* v. *Baird*, *supra* note 25, supports the proposition that the premarketing clearance provisions are not in conflict with a right of privacy. This court held that unmarried individuals have a privacy right to purchase and use contraceptives, but noted that the contraceptives themselves, if they are new drugs within the meaning of the Federal Food, Drug and Cosmetic Act, would be subject to pre-market approval and the safety and efficacy standards. Laetrile has not passed that hurdle of pre-market approval.

Thus, the decision of the federal appeals court that there is no right of privacy to choose medications that have not passed the premarket clearance procedures of the federal drug laws is in accord with the decisions of this Court and does not provide an appropriate vehicle for certiorari.

CONCLUSION

The federal appeals court's interpretation of the federal drug laws on the grandfather and privacy issues is consistent with the opinions rendered in analogous cases by this Court. The decision by the federal appeals court is in keeping with the principles enunciated by this Court, and reinforces the protections provided by State and federal law for patients with life-threatening illness. For these reasons, Mr. Rutherford's petition should be denied.

Respectfully submitted,

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